REMARKS

Claims 50-52 and 54-57 are pending in this application. Claims 1-49 and 53 have been cancelled without prejudice. Applicant reserves the right to prosecute the subject matter of any canceled claim in one or more continuation, continuation-in-part, or divisional applications.

Rejections Under §112

Claims 50-57 were rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the enablement requirement. The Examiner points out that the claims recite specific monoclonal antibodies and hybridoma cell lines that were deposited with the American Type Culture Collection (ATCC). However, the Examiner is unclear as to whether the deposited monoclonal antibodies and hybridoma cell lines have been made under the terms of the Budapest Treaty.

A Statement Under 37 CFR § 1.808 is hereby submitted confirming that all restrictions imposed by the depositor on the availability to the public of the above deposited material will be irrevocably removed upon the issuance of a patent for the above patent application deposited monoclonal antibodies and hybridoma cell lines. Accordingly, Applicant respectfully requests withdrawal of this rejection.

Claim 53 was rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the enablement requirement. The Examiner alleges that the specification does not disclose how to use the monoclonal antibodies of the invention as a pharmaceutical and thus undue experimentation would be required to practice the invention. Applicant respectfully disagrees. However, solely in order to further prosecution and in no way admitting that claim 53 is not enabled, Applicant has cancelled the claim.

For the above reasons, Applicant respectfully requests reconsideration and withdrawal of the rejections under §112.

Rejection Under §102

Claims 51, 53-55, and 57 were rejected under 35 U.S.C. §102(b) as anticipated by Rose et al., 1994, Hybridoma 13:221-227 ("Rose"). The Examiner alleges that the claims encompass the CR101 monoclonal antibody described in Rose and as such CR101 would be anticipatory. Applicant respectfully disagrees.

Applicant would like to point out that the claims as currently pending encompass monoclonal antibodies MoAb 51.2, MoAb 37.14, MoAb 109.12, MoAb 26.1, and competitive inhibitors of the same. Such antibodies recognize a glycosylated antigen on small cell lung cancer cells that is about 200 kDa as determined by SDS-PAGE under reducing conditions (see, *e.g.*, paragraph 17, lines 3-6 of the instant specification). When the antigen recognized by the antibodies of the present invention is deglycosylated, it is a single protein of slightly less than 98 kDa is resolved by SDS-PAGE (see, *e.g.*, Figure 2 and the last full paragraph in the first column on page 371 of Kruger et al., 2003, Cancer Immunol. Immunother. 52:367; previously submitted with the Amendment Under 37 C.F.R. §1.111 filed June 28, 2005). In the Office Action mailed September 21, 2005, the Examiner has characterized the antigen to which the antibodies of the invention bind as having a molecular weight of slightly less than 98 kDa when glycosylated (see the paragraph spanning pages 5 and 6 of the Office Action). Applicants would like to clarify that it is only in the deglycosylated state that the recognized antigen is of that molecular weight.

The Examiner contends that the antigen recognized by the monoclonal antibodies of the invention and monoclonal antibody CR101 of Rose bind the same antigen. The Examiner states that both antigens are present on SCLC cells and have molecular

weights of about 200 kDa when glycosylated and slightly less than 98 kDa when unglycosylated. Applicants respectfully disagree. According to Rose, the antigen recognized by CR101 is a highly glycosolated cell surface antigen associated with SCLC that resolves as *two proteins* of 94 kDa and 115 kDa by SDS-PAGE after enzymatic removal of the associated sugars (see, *e.g.*, the Abstract, the last paragraph on page 221, Table 1, and Figure 6 of Rose). Clearly Rose, the scientist conducting the experiments and examining the original data is in a better position to characterize the data than the Examiner. Nowhere does Rose claim that the antigen recognized by CR101 is a *single protein* of slightly less than 98 kDa when deglycosylated as is the antigen recognized by the antibodies of the present invention. Furthermore, the Examiner is equating the term "94 kDa" with the term "slightly less than 98 kDa". The rejection of the claims based on the Examiner's opinion, without additional evidence, is impermissible. *See, e.g.*, In re Zeidler, 682 F.2d 961, 967 (CCPA 1982). Thus, the Examiner is invited to provide additional evidence as to why the terms are equivalent and why the scientist, who have seen the original gels rather than photocopied portions, have chosen to characterize the molecular weights as such if she is in disagreement with the foregoing assertion.

Additionally, even assuming *en arguendo*, that the antigens recognized by the CR101 antibody and the antibodies of the invention are the same, the presently pending claims do not encompass all antibodies that bind to the antigen. Rather, the claims are directed to antibodies that bind to the same epitopes as the deposited antibodies. An antigen has many epitopes that have the potential to be recognized by an antibody. As such, one cannot assume that CR101 binds to the same antigen as any of the antibodies of the present invention.

Because of the similarities between the antigen that is recognized by the claimed antibodies and the antigen that is recognized by Rose's CR101 monoclonal antibody and because the Patent Office does not have the facilities and resources to provide factual evidence needed to establish that Rose does not report an antibody that is encompassed by the present claims, the Examiner has informed the Applicant that the burden of such proof lies with the Applicant. The Examiner has cited In re Best 562 F.2d 1252 as authority for the shift of the burden to the Applicant.

Applicant contends that the situation described in In re Best is distinguishable from the present situation. Specifically, the burden is shifted to the Applicant *only* where claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes. See In re Best, *supra* at 1255. Applicant submits that there is no evidence that the claimed compositions are identical or substantially identical to the preparation described in Rose. The improper basis for the rejection is the Examiner's speculation that because two antigens have some similar characteristics that they are indeed identical. As such, the burden of proving that Rose's CR101 and the antibodies of the present invention are identical has not properly shifted to the Applicant.

"A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." In re Paulsen, 30 F.3d 1475, 31 USPQ2d 1671 (Fed. Cir. 1994). CR101 of Rose is not encompassed by the present claims and thus does not meet each and every claim limitation.

For the above reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection under §102.

Rejection Under §103

Claims 51 and 52 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rose in view of Ward, 1992, Antibody Engineering, WH Freeman and Company, Car and Borrenbaek, ed. Pages 122-123 ("Ward"). The Examiner alleges that because the monoclonal antibodies of the invention are taught by Rose, Fab fragments of the antibodies are obvious to make in view of Ward. Applicant respectfully disagrees.

A finding of obviousness under 35 U.S.C. § 103 requires a determination of the scope and the content of the prior art, the differences between the invention and the prior art, the level of the ordinary skill in the art, and whether the differences are such that the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. Graham v. Deere, 383 U.S. 1 (1966). The relevant inquiry is whether the prior art suggests the invention, and whether one of ordinary skill in the art would have had a reasonable expectation that the claimed invention would be successful. In re O'Farrell, 853 F.2d 894, 902-4 (Fed. Cir. 1988); In re Vaeck, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991). Both the suggestion of the claimed invention and the expectation of success must be in the prior art, not in the disclosure of the claimed invention. In re Dow Chemical Co., 5 U.S.P.Q. 2d 1529 (Fed. Cir. 1988).

Applicant contends that the antibodies encompassed by the present claims are not reported by Rose for the reasons discussed *supra*. As such, Fab fragments of the novel antibodies of the invention are not obvious. Applicant acknowledges that Fab fragments in general were known at the time of the invention, however, Fab fragments of the particular antibodies of the present invention were not known.

For the above reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection under §103.

CONCLUSION

It is believed that the elected claims are in condition for allowance. Favorable action by the Examiner is earnestly requested.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 3828-4001US1.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

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